United States
Securities and Exchange Commission
Washington, D.C. 20549

Form 8-K

Current Report
Pursuant to Section 13 or 15(d)
Of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 14, 2020

Aileron Therapeutics, Inc.
(Exact Name of Company as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38130
(Commission
File Number)

13-4196017
(IRS Employer
Identification No.)

490 Arsenal Way
Watertown, MA
(Address of Principal Executive Offices)

02472
(Zip Code)

Registrant’s telephone number, including area code: (617) 995-0900

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<table>
<thead>
<tr>
<th>Title of each class</th>
<th>Trading Symbol</th>
<th>Name of each exchange on which registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Stock, $0.001 par value per share</td>
<td>ALRN</td>
<td>Nasdaq Capital Market</td>
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</table>

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒
Item 7.01    Regulation FD Disclosure.

On September 14, 2020, Aileron Therapeutics, Inc. (the “Company”) posted a Corporate Overview presentation on the “Investors & Media” section of the Company’s website (www.aileronrx.com).

The information in this Item 7.01 is furnished under Item 7.01 of Form 8-K and shall not be deemed “filed” for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01    Other Events

On September 14, 2020, the Company announced that it plans to report top-line final data for the dose optimization part of the open-label dose optimization and schedule optimization Phase 1b portion of its Phase 1b/2 clinical trial of ALRN-6924 in patients with small cell lung cancer (“SCLC”) at the 2020 EORTC-NCI-AACR conference. The Company continues to expect to report preliminary schedule optimization data in the fourth quarter of 2020.

The Company plans to initiate a clinical trial of ALRN-6924 in healthy volunteers to characterize the time to onset, the magnitude and the duration of cell cycle arrest in human bone marrow relative to ALRN-6924 administration in the fourth quarter of 2020.

Subject to the results of the healthy volunteer study and data from the dose- and schedule-optimization trials, and to obtaining sufficient funding, the Company expects to initiate Phase 1b/2 clinical trials in non-small cell lung cancer in the second half of 2021 and in a gastrointestinal cancer indication at an as yet undetermined time. The Company does not currently plan to conduct additional development of ALRN-6924 in patients with SCLC.

Forward-Looking Statements

Statements in this report and Exhibit 99.1 about Company’s future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements about the Company’s strategy and clinical development plans. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including whether the Company’s cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; whether results obtained in preclinical and nonclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether preliminary or interim results from a clinical trial will be indicative of the final results of the trial; whether the Company’s product candidates will advance through the clinical trial process on a timely basis, or at all; whether the results of such trials will warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether the Company’s product candidates will receive approval from regulatory agencies on a timely basis or at all; whether, if product candidates obtain approval, they will be successfully distributed and marketed; whether the coronavirus pandemic will have an impact on the timing of the Company’s clinical development, clinical supply and its operations; and other factors discussed in the “Risk Factors” section of the Company’s quarterly report on Form 10-Q for the period ended June 30, 2020, and risks described in other filings that the Company may make with the Securities and Exchange Commission. Any forward-looking statements contained in this report and Exhibit 99.1 speak only as of the date hereof, and the Company specifically disclaims any obligation to update any forward-looking statement, whether because of new information, future events or otherwise.
Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aileron Therapeutics, Inc.

Date: September 14, 2020

By: /s/ Richard J. Wanstall
Richard J. Wanstall
Chief Financial Officer and Treasurer